WORKING DRAFT

TECHNICAL DOCUMENT FOR CHARACTERIZING AND PRESENTING SUMMARY CHEMICAL EXPOSURE ASSESSMENT RESULTS

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Introduction

There is little debate among scientists that exposure is an integral part of understanding chemical safety. However, until recently, there has not been a great deal of consistency in how exposure information is reported, especially the results of individual monitoring and modeling studies. Such consistency would be desirable for the chemical industry, government, the public and other interested stakeholders. To help facilitate presentation of summary exposure information, the U.S. EPA has developed a series of sample exposure summary formats to provide those scientists and engineers who perform exposure evaluations with user-friendly, standard formats for presenting this information. The U.S. EPA expects that the use of these summary formats by industry will promote consistency in voluntarily reported exposure assessment results (encompassing consumer, occupational, and environmental exposures) for their chemicals. The approach builds on the reporting method already used in the Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) Program.

Background

The Chemical Right-to-Know Initiative was announced on the eve of Earth Day, 1998 and included the High Production Volume (HPV) Challenge Program, and the Voluntary Children's Chemical Evaluation Program (VCCEP). VCCEP is a program designed to provide data to enable the public to better understand the potential health risks to children associated with certain chemical exposures. Many of the chemicals selected for the VCCEP pilot are sponsored in the HPV Challenge Program and the health effects studies conducted in that Program will satisfy the Tier 1 test requirements of the VCCEP. Exposure is not a formal component of the U.S. HPV Program, and only limited exposure information is required in the OECD SIDS program. Some members of industry in the United States have expressed an interest in voluntarily developing exposure information on their chemicals to help put available hazard data (e.g., those developed under the U.S. HPV Challenge Program or the OECD SIDS program) into context. Given this interest, the U.S. Environmental Protection Agency is working with industry and other stakeholders to develop a format and associated instructions for summarizing this exposure information so that it is as useful as possible. The U.S. EPA believes that exposure information should be presented in a consistent manner, be transparent, be characterized in terms of the quality and completeness, and be available to the public. It is not the intention of the U.S. EPA to require exposure information as part of either the U.S. HPV Challenge Program or the OECD SIDS Program.

Characterizing and Presenting Summary Exposure Assessments

The Agency has developed draft summary formats for characterizing and presenting summary information for the key exposure assessment results. The use of these formats is complementary to exposure assessment frameworks that are used to focus an exposure assessment on key scenarios. The Agency recognizes that not all of the data identified when gathering information for an exposure assessment needs to be described using these formats. For example, if a number of monitoring studies were identified in the exposure assessment, key ones will usually be selected to estimate exposures. In this case, the exposure assessment would contain a list of all of the monitoring studies identified and the formats would be used to summarize the key studies that

were relevant to the exposure estimates presented. As another example, there may be cases where there are many sites where a chemical is used in an industrial process. This use may have environmental releases that can lead to children's exposure. If the assessment objective for this scenario is to generate conservative estimates of children's exposure using models, the sponsor may identify a few sites that are likely to give the highest exposures and generate model estimates of exposure for those sites. In this case the formats would be filled out only for those few sites. Thus, summary information may be presented both qualitatively, in a narrative fashion, and quantitatively using formats such as those presented herein.

These formats are not intended to be prescriptive. Rather, they provide a suggested flow of information. Four basic types of formats have been provided to address exposure information of interest to the Agency: (1) *General Information* summarizes information necessary to identify the chemical and assess its volume in the marketplace, and also provides the name of the company and technical contact for the information provided on the chemical; (2) *Summary of Releases and Exposure* summarizes the ways in which the chemical is manufactured and processed, the activities and practices of users, potential exposures, and any controls that are in place to limit exposure for a specific activity; (3) *Monitoring Evaluations* summarize information on direct measurements of chemical exposure for a specific use or release; and (4) *Modeling Evaluations* summarize evaluations using mathematical models that predict exposure to a chemical for a specific use or release. Exhibits 1-4 depict the four format types.

For each chemical for which information is provided, a *General Information* format should be completed. When providing information on a specific activity (e.g., chemical manufacturing) the sponsor should also complete the *Summary of Releases and Exposure* format. *Summary of Releases and Exposure* formats should be completed for <u>each</u> separate activity associated with the assessment (e.g., manufacturing, processing, and each of the various uses). Non-specific exposures (i.e, those exposures not associated with a specific activity or use) need not have an associated *Summary of Releases and Exposure* format completed if it is not relevant. In addition, for each release type summarized in a *Summary of Release and Exposure* format, available monitoring or modeling data should be summarized in the *Monitoring Evaluations* and *Modeling Evaluations* formats. In some cases, a chemical may have been evaluated in one or more monitoring studies intended to measure human exposures, environmental media concentrations or for some other purpose. Likewise, more than one modeling study may have been conducted. *Monitoring Evaluations* and/or *Modeling Evaluations* formats should be provided for each key scenario (e.g., outdoor air exposures to children in the communities where the manufacturing plant(s) are located, occupational exposure to workers involved in chemical manufacture, etc.) for which there are quantitative estimates of exposure. Therefore, there may be multiple *Monitoring Evaluations* and *Modeling Evaluations* formats associated with each *Summary of Releases and Exposure* format. Figure 1 provides a graphical representation of the organizational patterns of the four formats. Figure 2 presents an example of the assembled formats in a complete submission.

As mentioned above, in some cases it may not be possible to relate the measured exposure or environmental media concentration from a monitoring study to a particular activity (i.e., to chemical manufacturing or to the industrial, commercial or consumer product uses of the chemical).

However, the monitoring data are still useful for assessing exposures. In these cases, provide a *Monitoring Evaluations* format for key exposure estimates based upon this monitoring study.

To fully utilize the exposure information submitted, it is important that key exposure assessment results be reported in a consistent manner and that the completeness and quality of the results are adequately characterized. The Agency has developed several guidance documents that provide recommendations for developing exposure assessments that enable reviewers to more readily understand the assessment approach, assumptions, extrapolations made, data used, limitations and uncertainties of the data, and data gaps in a transparent and consistent manner (i.e., U.S. EPA, 1992a; U.S. EPA, 2000). For example, when exposure estimates are generated from monitoring data, summary information regarding the study objectives, the sampling and analytical methods, the level of quality assurance and quality control that was present in the study, and other key information should be communicated along with exposure estimates generated from the study. When exposure estimates are from models, key information such as the name of the model, the degree to which it has been evaluated, and the nature of the inputs (e.g., site-specific or conservative and generic) should accompany the exposure estimate. In describing the completeness of the assessment, the extent to which the potential environmental and human exposures associated with manufacturing, processing, use and disposal of a chemical have been assessed should be summarized. For those potential exposures that were not assessed, an explanation of why they were not assessed should be provided. Describing the quality of the exposure estimates is also important. The quality of the estimates should be adequate to support the decision to be made. A description of the quality is an important consideration when making a decision about whether the chemical is a candidate for further assessment or a candidate for initiation of risk management activities.

The remainder of this guidance document provides instructions for completing the exposure formats, resources and references, and glossary of terms. Examples of exposure summary formats are provided in a separate document.

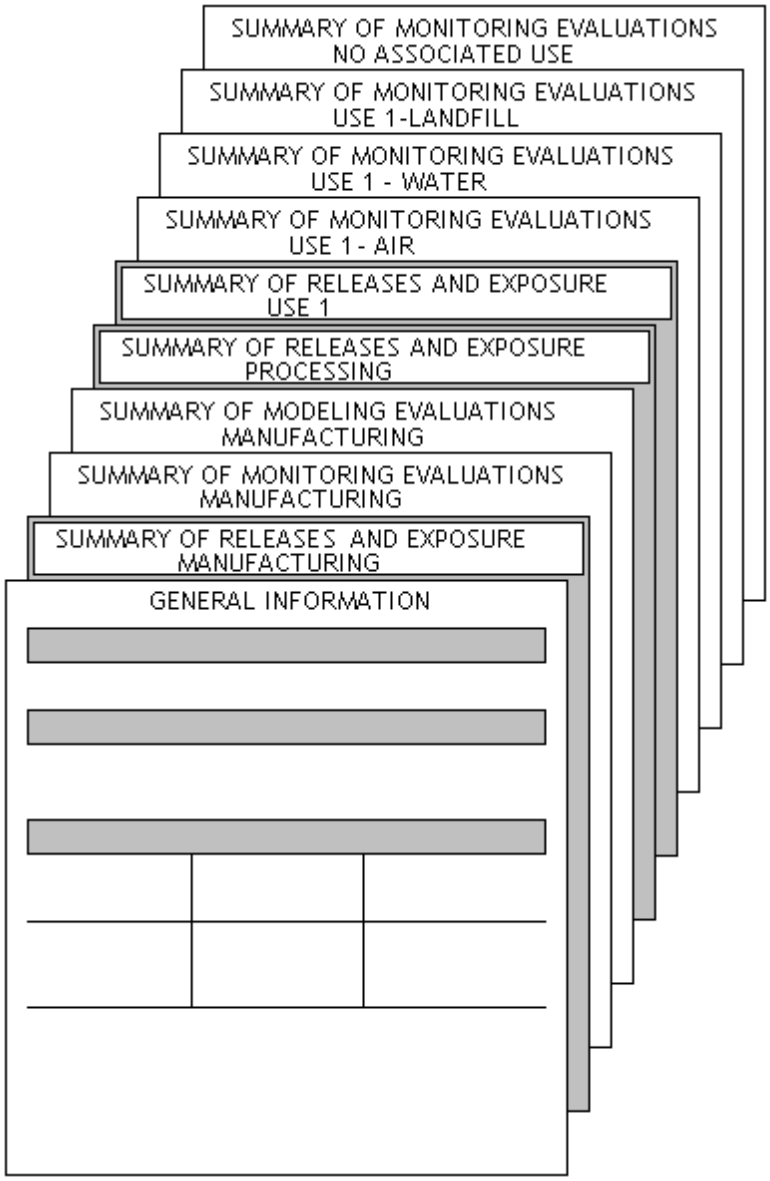

Figure 2. Example of Exposure Formats in a Complete Submission

Page ___ of ___
Chemical:_____
CAS Number:_____

EXHIBIT 1. GENERAL INFORMATION

1. Originator

a. Originator Name

b. Technical Contact

c. Submittal Date

2. Chemical ID

a. Name

b. Synonyms

c. CAS #

d. Physical/Chemical Properties

Physical Form (neat)		Photolysis
Molecular Weight (g/mol)		Hydrolysis
Octanol-water partition coefficient		Biodegradation
Vapor Pressure (25°C) (mm Hg)		Transport/distribution
Water Solubility (25°C) (mg/L)		
Melting Point (°C)		
Boiling point (°C)		
HLC (25°C) (atm-m^3/mol)		
Density (25°C) (g/mL)		

3. Volume and End Use

a. Volume	Units	Total US		Assessed	
	☐ pounds ☐ kilograms	Volume/year	Percent	Volume/year	Percent
	Manufactured				
	Imported				
	Total				
b. Uses	Use 1				
	Use 2				
	Use 3				
	Other				
	Export				

3. Volume and End Use (Continued)

c. Lifecycle Diagram

4. Executive Summary

a. Characterization of Completeness

b. Synthesis of Key Assessment Results

c. Discussion of Key Uncertainties, Limitations, and Data Gaps

d. Summary of Data Collection Effort

e. Contents	Summary of Releases and Exposure	Summary of Monitoring Evaluations	Summary of Modeling Evaluations

f. Table of Exposure Results **Scenario**	**Acute Exposures APDR (mg/kg/day)**	**Chronic Exposures ADD (mg/kg/day)**	**Population**

5. References

Page ___ of ___
Chemical:_____
CAS Number:_____

EXHIBIT 2. SUMMARY OF RELEASES AND EXPOSURE

Activity #: ___ Description: _____

1. Activity and Associated Volume

Activity type	Function/Application/Setting	Volume
☐ Manufacturing		
☐ Processing/Formulation		
☐ Use		

2. Physical Form and Concentration

As received:

Form:	☐ Dry Powder	☐ Pellets or Large Crystals	☐ Water or Solvent Wet Solid	☐ Gas or Vapor	☐ Liquid	☐ Other

Concentration:

As it leaves the site:

Form:	☐ Dry Powder	☐ Pellets or Large Crystals	☐ Water or Solvent Wet Solid	☐ Gas or Vapor	☐ Liquid	☐ Other

Concentration:

Description:

3. Site Information

a. Site Type

☐ Residential

☐ Commercial/Institutional

☐ Industrial

b. Number of Sites	Total U.S. Sites (indicate if estimate)	Sites addressed in this assessment

c. Site Locations

Page ___ of ___
Chemical:_____
CAS Number:_____

EXHIBIT 2. SUMMARY OF RELEASES AND EXPOSURE

Activity #: ___ Description: _____

4. Process Description

5. Release Information

Specify units: lbs Or kgs	Estimated Total Annual Releases	# days/year release occurs
A. On-site Air Release		
Fugitive	_____	_____
Stack	_____	_____
Basis for Estimate (attach additional calculations as desired):		
B. Water Releases from Site		
Water Releases	_____	_____
Receiving water name:	NPDES #:	
Basis for Estimate (attach additional calculations as desired):		
C. On-Site Land Releases		
Landfill	_____	_____
Land Treatment/ Land Amendment	_____	_____
Surface Impoundment	_____	_____
Underground Injection	_____	_____
Other (specify)	_____	_____
Basis for Estimate (attach additional calculations as desired):		

Page ___ of ___
Chemical:_____
CAS Number:_____

EXHIBIT 2. SUMMARY OF RELEASES AND EXPOSURE

Activity #: ___ Description: _____

5. Release Information (Continued)

D. Off-site Transfers

D1. Transfer to Publicly Owned Treatment Works (POTWs)

	Estimated Total Annual Releases	# days/year release occurs
	_____	_____

POTW Name:

Street Address:

City: County:

State: Zip Code:

NPDES number:

Basis for Estimate (attach additional calculations as desired):

Specify units:
lbs Or kgs

D2. Transfers To Other Off-Site Locations

	Estimated Total Annual Releases	# days/year release occurs
Incineration	_____	_____
Wastewater Treatment (Excluding POTW)	_____	_____
Underground Injection	_____	_____
Hazardous Waste (RCRA Subtitle C) landfill	_____	_____
Other landfill	_____	_____
Recycle or Recovery	_____	_____
Unknown or Other	_____	_____

Basis for Estimate (attach additional calculations as desired):

Page ___ of ___
Chemical:_____
CAS Number:_____

EXHIBIT 2. SUMMARY OF RELEASES AND EXPOSURE

Activity #: ___ Description: _____

6. Engineering Controls, Personal Protective Equipment, and Regulatory Requirements

a. Engineering Controls

b. Personal Protective Equipment

c. Regulatory Requirements

Occupational Standards:
TLV: _____
PEL: _____
STEL: _____

Federal Environmental Standards:
TRI: _____
HAP: _____
CWA Priority Pollutant: _____
RCRA U&P Waste: _____
Others: _____

SWDA contaminant: _____
CERCLA reportable quantity: _____

7. Summary of Exposure Results

Occupational, General Population, and Consumer Exposure Summary:

(1) Activity	(2) Physical Form		(3) Number of Persons Exposed	(4) Maximum Duration	
	(a) Form	(b) Conc.		Hours/day	Days/year

Page ___ of ___
Chemical:_____
CAS Number:_____

EXHIBIT 2. SUMMARY OF RELEASES AND EXPOSURE

Activity #: ___ Description: _____

8. References

9. Contents

Summary of Monitoring Evaluations Associated with this Release	Summary of Modeling Evaluations Associated with this Release

Page ___ of ___
Chemical:_____
CAS Number:_____

EXHIBIT 3. SUMMARY OF MONITORING EVALUATIONS

Activity #: ___ Description: _____
Evaluation:__ Description: _____

1. Technical Contact

a. Name

b. Phone Number

c. E-mail Address

2. Date of Monitoring Study

3. Monitoring Study Objective

4. Exposure Assessment Objective

5. Sampling Methods

6. Analytical Chemistry Methods

7. QA/QC Procedures

8. Results

a. Monitoring Results

b. Exposure Estimates

9. Uncertainty

10. References

Page ___ of ___
Chemical:_____
CAS Number:_____

EXHIBIT 4. SUMMARY OF MODELING EVALUATIONS

Activity #: ___ Description: _____
Evaluation:__ Description: _____

1. Technical Contact

a. Name

b. Phone Number

c. E-mail Address

2. Modeling Study Objective

3. Model Name, Version Number, Run Date

4. Evaluation/Peer Review Status of Model

5. Availability of Model

6. Key Model Inputs

7. Model Algorithm/Assumptions

8. Description of Exposure Scenario

9. Results

10. Uncertainty

11. References

Instructions For Completing The Exposure Formats

GENERAL INFORMATION

The major purpose of the General Information format is to provide basic identification information on the originator, chemical, and exposure assessment that follows.

1. Originator

a. Originator Name
Originator's name and address.

b. Technical Contact
Provide the name, address, phone number, fax, and email address for a technical contact person.

c. Submittal date
Enter the date that the exposure assessment was transmitted to the EPA.

2. Chemical ID

a. Name
Enter the name of the chemical from the HPV Challenge Program if the chemical is an HPV chemical. It is advisable to use the 9th Collective Index Chemical Abstracts index name or search the STN International for the name of the chemical.

b. Synonyms
In this field, list the various identities a product may have, including trade names, common names and synonyms. If a category approach is being used, provide the name of each chemical in the category in this field.

c. CAS #
The Chemical Abstracts Service (CAS) number can also be used as a primary cross-referencing identifier for synonyms, and also with categories. If the category approach is being used, provide the CAS number of each chemical in the category in this field.

d. Physical/Chemical Properties
Enter the following data for the chemical being evaluated. Indicate whether the data are measured or estimated. It is advisable that for HPV chemicals, including the VCCEP chemicals, information that already exists or is being developed as part of the HPV Challenge Program or as part of the OECD SIDS Program be used. Guidance for reporting the properties can be obtained from HPV Challenge and OECD SIDS guidance documents. When reporting the environmental transport and

distribution results, it is important to report the level of model used (i.e., Level I, II, or III) and the model input assumptions including the emissions scenario (e.g., equal loadings to air, water, soil).

Physical form [neat] Molecular weight [g/mol] Octanol-water partition coefficient Vapor Pressure [mmHg] Water Solubility [mg/L] Melting Point [°C] Boiling Point [°C] Henry's Law Constant [atm-m^3/mol] Density [g/mL]	Photolysis Hydrolysis Biodegradation Transport/distribution

3. Volume and End Use

a. Volume

Indicate the (U.S.) chemical volume including imports for the last calendar year, if known. Also, enter the volume covered by the reported exposure information. Ranges may be used as necessary to avoid CBI. Indicate whether the reported exposure information for the production/import volume is for a single U.S. company, for a subset of U.S. companies, for all U.S. companies, etc. Describe what fraction of the covered volume that is represented by each industrial, commercial, and consumer use. The goal is to account for 100% of the covered production/import volume of the chemical, although this may not always be possible. Total U.S. volume should be reported in either lbs/year or kg/year (use check boxes to indicate the appropriate units).

b. Uses

Describe the primary end uses of the chemical and the volume associated with each use. Include as many entries as are necessary to account for all of the production volume. It may be necessary to use estimates or ranges of volumes where exact information is unavailable. All known categories of products and their use should be included.

c. Lifecycle Diagram

Provide a description and/or a diagram of the lifecycle of the chemical, summarizing all steps between manufacturing and use. Indicate the percent of the manufactured chemical that is distributed to various intermediate and/or end uses. For example, the description may contain the following detail on the portion of the manufactured chemical that is:

1) Consumed internally for other chemical production.
2) Formulated or packaged by the producer.
3) Sold to distributors.
4) Sold for use in other chemical production (by the producer or by the distributor).
5) Sold to formulators or repackagers (by the producer or by the distributor).

4. Executive Summary

a. Characterization of Completeness

The Executive Summary should explain why the assessment was done and what questions were asked. The EPA's Guidelines for Exposure Assessment (U.S. EPA, 1992a) provides some suggestions for characterizing the completeness of the assessment. The level of detail or depth of the assessment is determined by the purpose of the exposure assessment and the resources available to perform the assessment. To conserve resources, most assessments are conducted in an iterative fashion, with a screening done first; successive iterations add more detail. After each iteration, the question is asked: Is this level of detail or degree of confidence good enough to achieve the purpose of the assessment? The Guidelines for Exposure Assessment recommend providing conclusions as to whether the questions posed were in fact answered, and with what degree of confidence. In addition, it is recommended that the executive summary describe the scope and level of detail of the assessment and whether the scope and level of detail were ideal for answering the questions of the assessment. Finally, the summary should address whether limitations in the scope and level of detail were made because of technical, practical, or financial reasons, and the implications of these limitations on the quality of the conclusions.

Information and data on production volume, key exposures associated with the activities for manufacturing, processing and use, and monitoring and/or modeling data and information is critical to determine whether the questions posed of the assessment have been adequately answered.

Characterize how completely the chemical volumes in item 3 above were accounted for. If all of the volumes were not accounted for, provide an explanation. Distinguish between total volumes and assessed volumes as appropriate. Describe the exposures that are associated with <u>each</u> of the activities described above and which of those exposures are assessed. For those exposures that are not assessed, provide an explanation. The exposures that should be addressed for manufacturing, processing and uses include direct exposures in occupational settings or through consumer use, indirect human exposures via environmental media such as surface water and outdoor air, and environmental or ecological exposures. In many cases, a scenario will not be relevant (e.g., if the chemical is being used in a closed process with no water releases, drinking water exposure may not be relevant). If an assessment is not provided, indicate why not. It is important that any gaps in the completeness of the assessment be explained. When describing the exposure, also describe the environmental releases associated with manufacturing, processing and the uses. However, characterization of releases or exposures as minimal, negligible, etc., without explaining the underlining rationale should be avoided.

Some monitoring studies (e.g. biomonitoring of the general population) may be difficult to associate with a specific manufacturing or commercial/consumer use. However, if the monitoring study may be used as the basis of one or more of the key exposure estimates (such as chronic exposure estimates), it should still be included along with an explanation that it cannot be related to a specific activity.

It may be helpful to ask these questions to determine whether completeness has been sufficiently characterized.

Does the summary provide a current total chemical volume, the assessed chemical volume, and how both of these volumes are broken out among uses? If it does not, does the summary provide an explanation of why it did not provide this information? For example, do CBI constraints limit quantification, or identification of downstream uses beyond the control of the assessor?

For each activity associated with the assessment (e.g., manufacturing, uses), does the summary estimate or otherwise address the range of exposure scenarios (source/pathway/route/population) that are possible (at least theoretically)? This range of exposure scenarios may include, depending upon the purpose and scope of the assessment, consumer product exposures to children and/or adults, indirect exposures to children and/or adults from releases to the environment, occupational exposures, and environmental (ecological) exposures. If one or more of the scenarios were not addressed, does the summary provide an explanation of why it was not addressed? Does the summary address aggregate exposures? If not, why not.

Are all sources of data cited in the summary given? Are the data sources readily available to persons seeking greater detail on procedures used to monitor the concentration of a chemical in the environment?

Are the experimental procedures and conditions given for generation of all reported experimental data or is reference provided to the protocols (i.e., sampling and analytical methods) followed in collecting experimental data? If not, why not?

In some cases monitoring data may exist that cannot be directly related to a particular activity (e.g., chemical manufacturing, use of the chemical in a consumer product), but is relevant to assessing exposures. Examples of this sort of monitoring data might be outdoor air monitoring data or biomonitoring data collected from national, regional or local surveys. Was an attempt made to identify and use existing monitoring data of this type? If so, what was done and what were the results? If this was not done, why not?

b. Synthesis of Key Assessment Results

Briefly summarize the results of the exposure assessment. Indicate the most significant endpoints of exposure and the methods by which they were identified and quantified. The key assessment results may be presented by activity (e.g. key exposures associated with uses, with manufacturing, etc.), by exposure pathway, or by some other way. This may be a qualitative summary of the key assessment results. The quantitative results should be summarized in the table discussed in 4f.

c. Discussion of Key Uncertainties, Limitations, and Data Gaps

Discuss the key overall exposure assessment uncertainties and limitations in this section. Specific uncertainties associated with a particular monitoring study or modeling study may be addressed in

the uncertainty sections of the monitoring or modeling formats. It is understood that often, 100% of total production volume will not be tracked. When this occurs, identify these limitations and the uncertainties that may stem from them. List data gaps not already covered under 4a.

d. Data Collection Effort

Explain the efforts involved in researching and collecting data for this exposure summary. Please indicate if this exposure reporting summary includes all of the monitoring data that were found or collected. If certain data were not used or reported in this summary, explain why.

e. Contents

Enter the number of release and exposure formats, and describe the associated formats for exposure estimates based on monitoring data and exposure estimates based on models.

f. Table of Exposure Results

For each exposure scenario, list the acute and chronic exposures (mg/kg-day) and identify the exposed population.

5. References

List references, citations, and resources used to prepare the form that are not provided elsewhere.

SUMMARY OF RELEASES AND EXPOSURE

The major purpose of the Summary of Releases and Exposure format is to provide basic exposure-related information on an activity. This format also facilitates the organization of more quantitative assessments from monitoring and modeling studies. Each format can be cross-referenced to the chemical or product of interest. This way, redundancy of information is minimized. Another function of the Summary of Releases and Exposure format is to use it to assess the potential for exposure through descriptions of use patterns and exposure controls. For manufacturing formats, address all releases and exposures from the manufacturing of the chemical.

Activity #:_____ Description:_____

This field comprises the title for this Summary of Releases and Exposure Format. Enter the activity number and a description (including activity type) of this Summary of Releases and Exposure format.

1. Activity and Associated Volume

Indicate the type of activity for which the Summary of Releases and Exposure format and associated Monitoring Evaluation and Modeling Evaluation formats are being prepared and check the appropriate box. Describe the activity. For example, activities could include: manufacture of the chemical; manufacture of a product that contains the chemical (processing); use of a product containing the chemical in an industrial setting; and use of a product containing the chemical in a commercial or consumer setting. If the activity is a use, describe the functional use application, and setting of the chemical. For example: 1) an adhesive (function) for wood products fabrication of underlayment (application) used in a residential dwelling (setting), 2) a filler (function) in caulking (application) used in construction of marine vessels (setting), and 3) a solvent (function) used in paint stripper (application) in an industrial setting (setting). Enter the volume associated with each activity. This volume can be reported as kg/year or lbs/year (A range may be used if necessary to avoid CBI).

2. Physical Form and Concentration

Use the checkboxes to indicate the physical form and concentration of the chemical as received and as it leaves the site. Enter the concentration of the chemical (ranges are acceptable). If the reported chemical substance is sent offsite in more than one form, report all of the physical forms.

In the description field, explain if and how the physical form of a product can influence the potential for exposure. For example, some chemicals can be distributed in different particle sizes, which would impact the likelihood of inhalation exposure. Also, in the case of product mixtures, other ingredients can lower the boiling point of the component being assessed, which could reduce the

potential for inhalation exposure. If a category approach is being used, the physical form(s) of each chemical in the category in this field can be provided.

3. Site Information

a. Site Type

This field allows for information on the location of the activity to be provided. Check off the appropriate checkbox: residential (if private consumption); commercial/institutional (professional using it); or industrial(manufactured). Multiple boxes may be checked if applicable. If the product described in this submittal is a residential product, enter "dispersed sites." If it is industrial, provide the number of sites associated with this use/release pattern. If the sites are known, provide their location in (c) below; otherwise, indicate that a generic release/use site is being assessed.

b. Number of Sites

Enter the total number of U.S. sites that are associated with this activity. If this is an estimate, indicate that here. Also enter the number of sites assessed in this assessment.

c. Site Locations

List the geographical location for each key site that is associated with this activity and assessed.

4. Process Description

This field allows for a description of the process associated with this activity. Provide a narrative description as well as a process flow schematic. The schematic should describe the manufacturing, processing, or use operation involving the chemical substance. The process flow schematic should:

(1) Identify the major unit operation steps and chemical conversions.
(2) Indicate the entry point of all feedstocks (e.g., reactants, solvents, catalysts) used in the operation.
(3) Identify each feedstock and specify its approximate weight (kg/day for continuous operations or kg/batch for batch operations).
(4) Number all points from which the chemical substance will be released into air, land, or water.
(5) Letter all points of potential worker exposure.

5. Release Information

Describe the environmental releases (to all media) for each manufacturing, processing, and use activity described in Section 1 above. These releases should be related back to the process description in Section 4, above. Note that disposal is considered a release. Be as quantitative and precise as possible (i.e., avoid the use of words such as *significant*, *sufficient*, *low*, *negligible*, etc., unless such words can be backed up by explanatory text.)

In this section, provide the estimate for the total media specific releases after on-site treatment of the chemical from the site. Provide the estimates of the releases by using monitoring data, which is preferable, or any other appropriate method. Estimates should be reported for the last calendar year. Specify the units in either in pounds or kilograms and maintain the same units throughout the summary.

Provide the estimate of the number of days per year the release occurs. Enter a whole number with a maximum of 2 significant figures.

Enter "NA" for release activities that are not associated with the chemical or "0" for releases less than 0.5 pounds per year (0.23 kgs/year).

A. On-site Air Releases

Provide the estimate of the total fugitive or non-point releases to air and the number of days/year the releases occur. This would include: equipment leaks from valves, pump seals, flanges, compressors, sampling connections, open-ended lines; evaporative losses from surface impoundments and spills; releases from building ventilation systems; and any other fugitive or non-point air emission.

In addition, provide the estimate of the total releases that occur through stacks, vents, pipes, or other confined air streams as stack or point source releases. Include storage tank emissions and releases from pollution control equipment. If desired, provide an estimate of the accuracy of the estimate of releases.

B. Water Releases From Site

Provide the estimate of the total releases of the chemical leaving the fenceline of the site from all discharge points to all streams or water bodies. Include all discharges from process outfalls such as pipes, open trenches, releases from on-site wastewater treatment, and contribution from storm water runoff, if applicable. Do not include discharges to a POTW or other off-site wastewater treatment facilities. If desired, provide an estimate of the accuracy of the estimate of releases. Often, releases due to routine cleanups (e.g., process cleanups or residual in containers), startup and turnaround deluge, are not accounted for, but should be included in the total releases.

C. On-site Land Releases

Provide the estimate the total releases of the chemical for each category of land disposal, if applicable. Provide estimates for only on-site release. Do not provide estimates of leaks from landfills separately. This should be accounted for in the estimate of total landfill release.

Releases to Land Treatment/Land Amendment include all waste containing the chemical that is applied or incorporated into soil on-site. Do not include waste that is landfilled.

Surface impoundments are natural topographic depressions, man-made excavations, or diked areas formed primarily of earthen materials designed to hold an accumulation of the chemical.

Other releases include any amount of the chemical that is released to land other than those listed. An example may be the accidental release of the chemical from an underground pipeline or storage tank.

Often, releases due to routine cleanups (e.g., process cleanups or residual in containers), startup and turnaround deluge, are not accounted for, but should be included in the total releases.

D. Off-Site Transfers

D1. Transfer to Publicly Owned Treatment Works (POTW)

Provide an estimate of the total quantity of the subject chemical, not the waste stream, transferred to the POTW. Include the geographical information for the POTW for each transfer.

D2. Transfers to Other Offsite Locations

In this section, provide the estimate the quantity of the subject chemical, not the waste stream, transferred and the accuracy of the estimate for each category listed. If the facility sends the subject chemical in waste to an off-site location where some of the chemical is to be recycled while the remainder to be treated, estimate each separately (i.e., waste treatment and recycle activities).

6. Engineering Controls, Personal Protective Equipment, and Regulatory Requirements

Complete these sections when relevant to the specific activity being presented.

a. Engineering Controls

Provide information on the specific types of engineering control equipment that are employed at the facility (e.g., ventilation hood, air pollution control equipment, a wastewater treatment plant, etc.). Identify which release points specified in Section 4 correspond to which engineering controls.

b. Personal Protective Equipment.

Provide information on the specific types of protective equipment that are employed to protect the worker from potential exposure (e.g., gloves, goggles, respirator, nitrogen blanket, etc.). Identify which release points specified in section 4 correspond to which personal protection equipment.

c. Regulatory Requirements

Describe any Federal, State, or local regulations that apply to the activities at the facility where the chemical is manufactured, processed, or used. Additionally, provide regulatory exposure limits, including occupational standards (e.g., PEL, STEL, TLV, etc.) and Federal environmental standards (e.g., Is the chemical a hazardous air pollutant? Is the chemical regulated under the Toxics Release Inventory? Clean Water Act priority pollutant? RCRA U&P waste? SDWA contaminant? OPPT MTL? CERCLA reportable chemical? TPQ under SARA?).

7. Summary of Exposure Results

This section is intended to provide a summary of the exposure assessment results that are associated with this activity and presented in more detail in attached formats for exposure estimates based on monitoring data and exposure estimates based on models. This section may also be used to qualitatively describe the exposures and to list and prioritize potential routes of exposure.

Describe which human and environmental exposures are associated with the activity described in Section 3 above. The human exposures may include direct exposure in occupational settings associated with an activity and direct exposures through use of consumer products. Human exposures may also include drinking water, outdoor air, food chain, and other indirect human exposures associated with environmental releases from an activity. The environmental exposures may include surface water, sediment, food chain, and other environmental exposures associated with environmental releases from an activity. Areas that can be addressed are potentially exposed populations, setting of use, frequency, duration, amounts per use, personal protection equipment, physical form, and activity.

Key occupational, general population, and consumer exposures should be presented using the table provided in the Exhibit, using the following guidelines:

(1) Describe the activities in which persons may be exposed to the chemical substance (e.g., product use, an environmental release, work activity such as bag dumping, tote filling, sampling, unloading drums, cleaning, etc.).

(2) (a) Indicate the physical form of the chemical substance (e.g., solid: crystal, granule, powder, or dust) at the time of exposure.

(b) Indicate the percent concentration of the chemical substance at the time of exposure.

(3) Provide (estimate) the maximum number of persons involved in each activity for all sites combined.

(4) Provide an estimate of the maximum duration of the activity for any worker in hours per day (< 0.25 hours/day, 0.25 - 1 hours/day, 1 - 8 hours/day, and > 8 hours per day) and days per year (< 10 days/year, 10 - 100 days/year, 100-250 days/year, > 250 days/year).

If exposure for an activity is not described, explain why (e.g., there is insufficient information to describe the exposure). If exposure is described as minimal, provide a rationale for this characterization.

8. References

This section provides an opportunity to list references used, citations and resources. Iinformation on the availability of the complete studies that have been summarized can also be provided.

9. Contents

Enter the titles of the summary evaluations for exposure estimates based on monitoring data and exposure estimates based on models. If no monitoring or modeling information is included, provide a rationale for the missing information.

If monitoring/modeling for an activity is not included, explain why (e.g., key monitoring/modeling have not yet been performed but will be, exposures via a particular pathway are not expected because...., etc.).

SUMMARY OF MONITORING EVALUATIONS

The monitoring evaluation format should be used to provide summary information on key monitoring studies in the exposure assessment. Key monitoring studies are those studies that are used to estimate exposures in the exposure assessment. Here, the term monitoring covers key studies in which data are the result of measurements of the chemical in environmental media (e.g., outdoor air, indoor air, surface water, soil, etc.) or a particular exposure scenario. It also includes measurements of biomonitoring data. The fields are flexible enough to include monitoring in any type of medium, including simple environmental matrices such as air or water or complex biological matrices like blood or tissue. When estimates of key environmental releases are based on a monitoring study, the monitoring evaluations format should be used to describe the study.

In exposure assessment it is common to encounter monitoring data that were specifically collected to perform a particular exposure assessment. It is also common to encounter monitoring data that might be useful for an exposure assessment, but were collected for other purposes. The monitoring format has separate fields for the monitoring study objective and for the exposure assessment objective. If the objective of the study design for the monitoring study is not the same as the objective of the exposure assessment, these to objectives need to be individually identified. There are also two separate fields for providing information on the results of the monitoring study and for providing the exposure assessment results. Fields are also included for information on the sampling and analytical methods used, the quality assurance and quality control procedures used and uncertainties in the assessment. Information provided in these fields is important for characterizing the quality of the assessment and for transparency. There is also a field provided for references where the reader may be directed to the full monitoring study report, to the full exposure assessment, or to other more detailed information relevant to this estimate of exposure. Monitoring studies that were identified as part of data gathering for the exposure assessment but were not used to estimate exposures are not considered key studies and the format would not need to be completed for these studies, though the exposure assessment should list them and identify where they may be found.

In some cases it may not be possible to relate existing monitoring data to a particular source or activity. A chemical may have been studied in one or more monitoring studies intended to measure human exposures of a particular population for purposes of a population exposure assessment, environmental media concentrations for a particular regulatory purpose, or for some other purpose. This monitoring data are still useful for assessing exposures and an attempt to identify existing monitoring data should be made. If data of this type are identified and are used to estimate exposures for the exposure assessment, they are key studies and this format should be used to report summary information on the monitoring study and the exposure estimates.

Activity #:_____ Description:_____
Evaluation: _____ Description:_____

Enter the activity number and description from the title of the Summary of Releases and Exposure Format. Enter an evaluation title and description for this Summary of Monitoring Evaluation Format.

1. Technical Contact

Provide the name, address, phone number, fax, and E-mail address for a technical contact person to whom any questions about the exposure estimate should be directed. This individual may or may not be the same as the overall technical contact provided in the General Information Format.

2. Date of Monitoring Study

Indicate the date(s) on which the study was conducted, including sampling dates, and laboratory analysis dates.

3. Monitoring Study Objective

In this section, describe the goals and objectives of the monitoring study. Identify the population, if any that was assessed, whether it was to assess acute or chronic exposures, and whether it was designed to estimate typical or conservative (i.e. protective) exposures. Include a brief description of the study design

Listed below are examples of the types of statements that may be included to describe the objectives of a study. One of these statements may be used if appropriate. If none are appropriate provide one that is.

- Monitoring data for the chemical of interest collected using a study design which will permit estimates of average and high-end (i.e., chronic, acute) exposures to the population of interest.
- Monitoring data for the chemical of interest collected on the population of interest for exploratory purposes, but not for estimating average or high-end (chronic or acute) exposures.
- Surrogate monitoring data (i.e., data not collected directly on the population or chemical of interest) but for a similar exposure scenario.
- Monitoring data lacks documentation on study design.

4. Exposure Assessment Objective

State the objective of the exposure assessment. Identify the population, that was assessed, and whether the study was designed to assess acute or chronic exposures. Also describe whether it was designed to estimate typical or conservative (i.e. protective) exposures. This objective may differ from the objective of the monitoring study if monitoring data were collected for some other purpose. For example, the objective of a monitoring study may have been to maintain a record of aquatic concentrations in compliance with state regulations to protect fish species, but the objective of the exposure assessment may be to use those concentrations to estimate exposure to humans via ingestion and dermal contact with the water. Examples of statements that may be used to describe the exposure assessment objective are below. Again, if none of these statements are applicable, then another needs to be provided.

- The exposure estimate is intended to be a generic conservative (protective) estimate of (acute or chronic) exposure to the population of interest for this scenario.
- The exposure estimate is intended to be a site-specific average estimate of (acute or chronic) exposure to the population of interest.
- The exposure estimate is intended to be higher than any expected (acute or chronic) exposure to the population of interest for this scenario.

5. Sampling Methods

Describe the sampling method used in this section. Listed below are examples of statements that sponsors may include to describe the sampling method used in the monitoring study. If it is appropriate, use one of these statements. If none are appropriate provide one that is.

- The sampling method used has been validated and accepted by an independent body (e.g., ASTM standard method xxxx, NIOSH method yyyy).
- The sampling method used is well documented and is method number 1234 developed by company ABC.
- The sampling method documentation is not available.

A discussion of the number of samples collected, when and where they were collected, how they were stored, and how they were transported should also be included in this section.

6. Analytical Chemistry Method

Describe where the laboratory analysis was conducted and what analytical chemistry method was used. Describe the method used (e.g., GC/MS) and the source (e.g., ASTM standard method xxxx, EPA test method yyyy, etc.)

Listed below are examples of statements that may be included to describe the analytical methods of a study. If it is appropriate, use one of these statements. If none are appropriate provide one that is.

- Monitoring data developed using analytical chemistry method that has been validated and accepted by an independent body (e.g., ASTM standard method xxxx, NIOSH method yyyy).
- Monitoring data analyzed developed using well documented analytical chemistry method (e.g., method number 1234 developed by Company ABC laboratory)
- Monitoring data analytical chemistry method documentation not available.

7. QA/QC Procedures

Describe how quality assurance and quality control (i.e., QA/QC) were addressed in the monitoring study. This may include laboratory procedures and also the analysis of the data. Provide a summary of the quality assurance objectives. Further procedural details on fortification levels, controls, etc., may be provided in a reference.

Listed below are some examples of statements that may be included to describe whether quality assurance objectives were met. If it is appropriate, use one of these statements. If none are appropriate provide one that is.

- Quality assurance objectives were set and met. Quality control procedures have been employed and documented.
- Quality assurance objectives were set, but not met for the following reasons …. Quality control procedures have been employed and documented.
- Quality assurance objectives were not set for this study. Quality control procedures have not been documented.
- Information on quality assurance objectives and quality control procedures could not be obtained (explain).

It may be helpful to ask these questions to determine whether the monitoring study and exposure estimates are sufficiently characterized:

For exposure estimates that relied on environmental monitoring data to estimate exposures, did the summary provide a statement of the objective of the monitoring study (e.g., data were collected to estimate average and high end exposures, data were collected for exploratory purposes, etc.)? If the summary does not provide the objective of the monitoring study, why not?

In addition to providing a statement of the objective of the monitoring study, a statement of the objective of the exposure estimate generated from the monitoring data should be provided. For

example, an assessment might use the highest value found in a monitoring study to generate a conservative estimate of exposure. Alternatively, the assessment might use average value from the monitoring study to generate a typical exposure. Did the summary provide a statement of the objective of the exposure estimates? If not, why not?

If monitoring data are used as inputs to estimating exposure, are the sampling and analytical methods identified (e.g., ASTM Standard)? If not, why not? This is important in evaluating the quality of the data.

If monitoring data are used as input to estimating exposure, is the QA/QC that was employed in the monitoring study described? If not, why not? This is important in evaluating the quality of the data.

8. Results

a. Monitoring Results

Enter a summary of the results of the monitoring study. If a subset of the results are used in the exposure estimate described below, provide that information here too. The numerical results including the units should be provided.

b. Exposure Estimates

Enter a description of the equation used to estimate exposure (or intake, or dose) and the values and sources of each input to the equation. There are various equations and methods that may be used for providing estimates of exposure such as an equation for estimating ppm hours exposure or selection of an estimate of peak exposure concentration over a specified time interval. In exposure assessment it is also common to use equations for providing estimates of dose and intake such as average daily dose (ADD), lifetime average daily doses (LADD), average daily intake, etc. The data provided by the monitoring study would be one input. Other inputs could include things like breathing rate, duration of exposure, body weight, skin surface area in contact with a contaminant, etc., depending on the equation. For information on the definitions and equations for these and other estimates of exposure, dose and intake, EPA's 1992 Guidelines for Exposure Assessment is a valuable resource. Listed below are examples of statements that may be included to characterize the inputs. If none of these statements are appropriate, provide ones that are. If an exposure estimate is characterized as being average, conservative, etc., provide the basis for that statement.

- The inputs are intended to provide an estimate of average (acute or chronic) exposure, intake or dose to the population being assessed.
- The inputs are intended to provide a conservative estimate of (acute or chronic) exposure, intake or dose to the population being assessed.

If biological monitoring data are being used to reconstruct a dose, this section also provides a place to summarize how this was done and what assumptions were made.

This section is also the place where the characteristics of the exposed population that is being assessed should be described (e.g., size of the assessed population, age of the assessed population, location of the assessed population if that is relevant,). Remember that when exposure is characterized as being average, conservative, etc., it should refer to the exposed population and the type of exposure being estimated (i.e. acute or chronic exposure).

9. Uncertainty

As with other types of scientific inquiry, there are limitations and uncertainties. In this field, address the major sources of uncertainty in the exposure estimate, including monitoring study limitations, assumptions made about the behavior of exposed populations, or other factors. Identification of data gaps and the need for more data for the assessment can be included here.

10. References

This section provides an opportunity to list references used, citations and resources. Information on the availability of the complete studies that have been summarized can be provided.

SUMMARY OF MODELING EVALUATIONS

This format should be used whenever a model is used to estimate key environmental concentrations that are subsequently used to estimate key exposures.

This format may also be used in the event that an environmental concentration is used that is neither the result of monitoring data or estimated using a model (e.g., a dose is being estimated for dermal exposure to a liquid consumer product and the concentration of the chemical in the product is known through formulation data).

Although the word model is often associated with scientific computer software applications, it can also be used to describe one or more algorithms or mathematical equations. Models can be used to make estimates of a chemical concentration in an environmental media and to make subsequent estimates of exposure. It is also true that estimates of exposure (i.e., concentration * duration of contact), and dose (e.g. daily intake, absorbed dose) are all generated using "models". The environmental concentration used to estimate exposure or dose may come from a model or monitoring data.

In exposure assessment, the model used to estimate environmental concentrations plays a very important role. When appropriate monitoring data are not available, the estimation of an environmental concentration using a model is often the most sensitive step in accurately estimating subsequent exposures and doses. It is important to identify the model and the assumptions that were used whenever a model is used to estimate the environmental concentrations.

Important factors in characterizing the quality of exposure estimates based upon models and providing transparency include the values and sources of model inputs, the model algorithm, the level of model evaluation and presence or absence of peer review. There are also models that use the outputs of other models as inputs. The Modeling Evaluation Format is flexible enough to allow a description of the diverse approaches to modeling exposure.

Activity #:_____ Description:_____
Evaluation: _____ Description:_____

Enter the activity number and description from the title of the Summary of Releases and Exposure format. Enter an evaluation title and description for this Summary of Modeling Evaluation format.

1. Technical Contact

Provide the name, address, phone number, fax, and email address for a technical contact person to whom any questions about the exposure estimate should be directed. This individual may or may not be the same as the overall technical contact provided in the General Information Format.

2. Modeling Study Objective

This section is used to describe the scope and intent of the study. When using a model to estimate environmental media concentrations and exposures, it is common to do these at the same time and as part of the same study. In this case it is not necessary to separately discuss the objective for estimating the media concentration and the objective for the exposure assessment. State whether the objective was to provide a conservative estimate of exposure, a representative estimate of exposure or some other kind of estimate of exposure. Identify the population being assessed and whether the study is intended to estimate acute or chronic exposures or both.

3. Model Name, Version Number, Run Date

This section is used to provide a the name of the model, and a brief description, sufficient enough to allow the reader to understand the kind of model used. Also provide the version number of the model and the date(s) on which the model was run.

4. Evaluation/Peer Review Status of Model

Models may go through an evaluation process using data from monitoring studies. In some cases this evaluation using monitoring data may constitute a formal validation of the model performance. A model may also be evaluated against other models.

Models can also be subject to peer review. A peer review is done by experts and can include such things as a review of a model's algorithm and the implicit assumptions involved in that algorithm, a review of default values for input parameters and a review of whether the model's programming carries out necessary calculations in an accurate manner.

Describe any model evaluations and/or peer reviews that have been performed in this section. If the model has undergone an evaluation, provide information on how the model performed and some background information about the evaluation (i.e., how input data were selected, was the model validated against field observations or against other models? etc.).

Listed below are examples of statements that may be included to address validation and peer review. If none of these statements are relevant, provide one that is.

Model evaluation

a. The model has been validated with monitoring data that is directly relevant for the scenario of interest.
b. The model has been evaluated monitoring data that is relevant to the scenario of interest, but it has not been formally validated.

c. The model has not been validated or evaluated with monitoring data.

Model peer review

a. The model has been through a formal peer review process.
b. The model has been informally peer reviewed.
c. The model has not been peer reviewed.

It may be helpful to ask these questions to determine whether the modeling study and exposure estimates are sufficiently characterized:

If a model is used to estimate an environmental concentration, is the model evaluation/validation status described? If not, why not? This is important in evaluating the quality of the data.

If a model is used to estimate environmental concentrations, was the peer review status of the model described? If not, why not? This is important in evaluating the quality of the data.

If the summary used a model to estimate environmental concentrations, are the key assumptions in the model algorithm described? If not, why not. This is important in evaluating the quality of the data.

Did the summary provide the values and sources of key inputs used in estimating concentrations and exposures? If not, why not? This is important in evaluating the quality of the data.

Are the units appropriate to all reported quantitative estimates provided? Are the dimensions correct? Are conversion factors used correctly? Are non-dimensional quantities correctly expressed? Is the number of significant figures given in dimensional quantities correct?

5. Availability of Model

Provide information on how to obtain the model, related guidance documents, evaluations and reviews that are not part of a peer review process, and any other information that may be relevant.

Generally speaking model availability may be described by one of the following categories:

I. A private model with limited release.
II. The model is available for purchase and the code is closed.
III. The model is available at no or low cost. The code is available for inspection only.
IV. The model is available at no or low cost. The code is available for inspection and modification.

6. Key Model Inputs

Provide the values, along with units, for key inputs used to estimate environmental media concentrations. Depending on the type of model used, these key inputs could include a release rate to the media of interest, the days of release, receiving stream flows, house volumes and air exchange rates, etc. The source of the input data should also be provided.

Some models use certain assumptions, which can appear as default values in specific equations. List the values and units of key inputs that were used in the assessments and of any changes to the defaults and provide a rationale for changing default values (e.g., direct measurements of habits and practices for the situation of interest). In addition to providing the values for key inputs, characterize the intent of the selections. Listed below are examples of statements that may be included to characterize the inputs used in a modeling study. If none of these statements are appropriate, provide one that is.

Inputs to model used to estimate environmental media concentrations

- The model used measured site or scenario specific values for key inputs
- The model used estimated site or scenario specific values for key inputs.
- The model used generic conservative default values for key inputs.

7. Model Algorithm/Assumptions

Describe the model algorithm and the assumptions that were made in running it. Example:

The model uses a modified advection-dispersion equation to predict contaminant concentrations in the vadose zone, and then uses an empirically-derived equation to determine uptake of the contaminant into food crops. The model assumes one-dimensional dispersion and first-order biodegradation.

8. Description of Exposure Scenario

Describe the exposure scenario used in evaluating the model. Include a description of the population being assessed, the source/pathway/route of exposure, whether it is an acute exposure or a chronic exposure, and whether the estimate is intended to be conservative, typical, etc. Example:
High end chronic estimates of exposure of the general public to contaminants metabolized through the roots of food crops.

9. Results

Describe the results of the model estimation of environmental media concentration. The values obtained, their units, and other relevant information (e.g., peak concentrations, average concentrations over a defined time interval and location, etc) should also be provided here.

Describe the equation used to estimate exposure (or intake/dose) and the values and sources of each input to the equation. There are various equations and methods that may be used for providing estimates of exposure such as an equation for estimating ppm * hours exposure or selection of an estimate of peak exposure concentration over a specified time interval. In exposure assessment, it is also common to use equations for providing estimates of dose and intake such as average daily dose (ADD), lifetime average daily doses (LADD), average daily intake, etc. The data provided by the model for an environmental media concentration would be one input. Other inputs could include things like breathing rate, duration of exposure, body weight, skin surface area in contact with a contaminant, etc., depending on the equation. For information on the definitions and equations for these and other estimates of exposure, dose and intake, EPA's 1992 Guidelines for Exposure Assessment is a valuable resource. Listed below are examples of statements that may be included to characterize the inputs. If none of these statements are appropriate, provide ones that are. If an exposure estimate is characterized as being average, conservative, etc., provide the basis for that statement.

- The inputs are intended to provide an estimate of average (acute or chronic) exposure, intake or dose to the population being assessed.
- The inputs are intended to provide a conservative estimate of (acute or chronic) exposure, intake or dose to the population being assessed.

This section is also the place where the characteristics of the exposed population that is being assessed should be described (e.g., size of the assessed population, age of the assessed population, the location of the assessed population and other relevant characteristics of the assessed population). Remember that when the exposure is characterized as being average, conservative, etc., it should refer to the exposed population and an acute or chronic exposure.

10. Uncertainty

Virtually all models have uncertainties and assumptions that affect their reliability. This section is where issues, including, for example, how the use of default assumptions affects that output of a model, relative precision, etc., may be discussed. Identification of data gaps and the need for more data for the assessment can be included here.

11. References

List references used, citations and resources. Also provide information on the availability of the complete studies that have been summarized.

RESOURCES/REFERENCES

U.S. EPA (2001) Standard Operating Procedures (SOPs) for Residential Exposure Assessments. Washington, DC: Office of Pesticide Programs.

U.S. EPA (2000) Science Policy Council Handbook: Risk Characterization. Washington, DC: Office of Science Policy, Office of Research and Development. EPA-100-B-00-002. December 2000.

U.S. EPA (2000) Estimating Exposures to Dioxin-Like Compounds. Washington, DC: Office of Research and Development. EPA/600/P-00/1005Cb.

U.S. EPA (1998) Series 875-Occupational and Residential Exposure Test Guidelines Group B: Postapplication Exposure. Washington, DC: Office of Prevention, Pesticides, and Toxic Substances.

U.S. EPA (1997) Exposure Factors Handbook. Office of Science Policy, Office of Research and Development, National Center for Environmental Assessment. Washington, DC. 20460. EPA/600/C-99/001.

U.S. EPA (1992a) Guidelines for Exposure Assessment. Washington, DC: Office of Research and Development, Office of Health and Environmental Assessment. EPA/600/Z-92/001.

U.S. EPA (1992b) Dermal Exposure Assessment: Principles and Applications. Washington, DC: Office of Health and Environmental Assessments. EPA/600/8-9/011F.

U.S. EPA (1990) Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions. EPA 600/6-90/003. Available from NTIS, Springfield, VA; PB-90-187055/AS.

U.S. Department of Agriculture (USDA) (1996a) Data tables: results from USDA's 1994 Continuing Survey of Food Intakes by Individuals and 1994 Diet and Health Knowledge Survey. U.S. Department of Agriculture, Agricultural Research Service, Riverdale, MD.

U.S. Department of Agriculture (USDA) (1996b) Data tables: results from USDA's 1995 Continuing Survey of Food Intakes by Individuals and 1995 Diet and Health Knowledge Survey. U.S. Department of Agriculture, Agricultural Research Service, Riverdale, MD. -520/1-84-015.

American Industrial Hygiene Council (AIHC) (1994) Exposure factors sourcebook. AIHC, Washington, DC.

GLOSSARY OF EXPOSURE ASSESSMENT TERMS

The definitions for many of the terms listed below were taken directly from EPA's 1992 Guidelines for Exposure Assessment. The remainder were derived from other sources.

Absorbed dose - See internal dose.

Absorption barrier - Any of the exchange barriers of the body that allow differential diffusion of various substances across a boundary. Examples of absorption barriers are the skin, lung tissue, and gastrointestinal tract wall.

Accuracy - The measure of the correctness of data, as given by the difference between the measured value and the true or standard value.

Activity - Action that describes the manner in which a chemical is used at a facility. Typical activities include manufacturing, processing, and/or otherwise using the chemical.

Administered dose - The amount of a substance given to a test subject (human or animal) in determining dose-response relationships, especially through ingestion or inhalation. In exposure assessment, since exposure to chemicals is usually inadvertent, this quantity is called potential dose.

Agent - A chemical, physical, mineralogical, or biological entity that may cause deleterious effects in an organism after the organism is exposed to it.

Aggregate Exposure - Total exposure that accounts for all routes of exposure including inhalation, dermal, and ingestion of the chemical.

Ambient - The conditions surrounding a person, sampling location, etc.

Ambient measurement - A measurement (usually of the concentration of a chemical or pollutant) taken in an ambient medium, normally with the intent of relating the measured value to the exposure of an organism that contacts that medium.

Ambient medium - One of the basic categories of material surrounding or contacting an organism (e.g., outdoor air, indoor air, water, or soil) through which chemicals or pollutants can move and reach the organism. (See also biological medium, environmental medium)

Applied dose - The amount of a substance in contact with the primary absorption boundaries of an organism (e.g., skin, lung, gastrointestinal tract) and available for absorption.

Arithmetic mean - The sum of all the measurements in a data set divided by the number of measurements in the data set.

Background level (environmental) - The concentration of substance in a defined control area during a fixed period of time before, during, or after a data-gathering operation.

Breathing zone - A zone of air in the vicinity of an organism from which respired air is drawn. Personal monitors are often used to measure pollutants in the breathing zone.

Bias - A systematic error inherent in a method or caused by some feature of the measurement system.

Bioavailability - The state of being capable of being absorbed and available to interact with the metabolic processes of an organism. Bioavailability is typically a function of chemical properties, physical state of the material to which an organism is exposed, and the ability of the individual organism to physiologically take up the chemical.

Biodegradation - the transformation of a chemical compound by the action of a living organism. This chemical property can be expressed as a half-life value ($t_{1/2}$) in units of time or as a reaction rate constant (k) in units of time^{-1}.

Biological marker of exposure (sometimes referred to as a biomarker of exposure) -Exogenous chemicals, their metabolites, or products of interactions between a xenobiotic chemical and some target molecule or cell that is measured in a compartment within an organism.

Biological measurement - A measurement taken in a biological medium. For the purpose of exposure assessment via reconstruction of dose, the measurement is usually of the concentration of a chemical/metabolite or the status of a biomarker, normally with the intent of relating the measured value to the internal dose of a chemical at some time in the past. (Biological measurements are also taken for purposes of monitoring health status and predicting effects of exposure.) (See also ambient measurement.)

Biological medium - One of the major categories of material within an organism (e.g., blood, adipose tissue, or breath) through which chemicals can move, be stored, or be biologically, physically, or chemically transformed. (See also ambient medium, environmental medium)

Biologically effective dose - The amount of a deposited or absorbed chemical that reaches the cells or target site where an adverse effect occurs, or where that chemical interacts with a membrane surface.

Blank (blank sample) - An unexposed sampling medium, or an aliquot of the reagents used in an analytical procedure, in the absence of added analyte. The measured value of a blank sample is the blank value.

Body burden - The amount of a particular chemical stored in the body at a particular time, especially a potentially toxic chemical in the body as a result of exposure. Body burdens can be the result of long-term or short-term storage, for example, the amount of a metal in bone, the

amount of a lipophilic substance such as PCB in adipose tissue, or the amount of carbon monoxide (as carboxyhemoglobin) in the blood.

Bounding estimate - An estimate of exposure, dose, or risk that is higher than that incurred by the person in the population with the highest exposure, dose, or risk. Bounding estimates are useful in developing statements that exposures, doses, or risks are "not greater than" the estimated value.

Characterization of Completeness - here, characterization of completeness of the exposure assessment refers to a description of how completely the chemical volumes are accounted for, which exposure scenarios associated with each activity were assessed, which exposure scenarios do not need to be studied with an explanation of why they don't need study and which exposure scenarios were otherwise not studied. Because not all exposure monitoring data can be associated with a particular activity (e.g., a national biomonitoring study for a chemical) the characterization of completeness also includes a description of the availability of this type of monitoring data. The extent to which aggregate exposures are addressed can also be included here.

Comparability - The ability to describe likenesses and differences in the quality and relevance of two or more data sets.

Data quality objectives (DQO) - Qualitative and quantitative statements of the overall level of uncertainty that a decision-maker is willing to accept in results or decisions derived from environmental data. DQOs provide the statistical framework for planning and managing environmental data operations consistent with the data user's needs.

Dose - The amount of a substance available for interaction with metabolic processes or biologically significant receptors after crossing the outer boundary of an organism. The potential dose is the amount ingested, inhaled, or applied to the skin. The applied dose is the amount of a substance presented to an absorption barrier and available for absorption (although not necessarily having yet crossed the outer boundary of the organism). The absorbed dose is the amount crossing a specific absorption barrier (e.g., the exchange boundaries of skin, lung, and digestive tract) through uptake processes. Internal dose is a more general term denoting the amount absorbed without respect to specific absorption barriers or exchange boundaries. The amount of the chemical available for interaction by any particular organ or cell is termed the delivered dose for that organ or cell.

Dose rate - Dose per unit time, for example in mg/day, sometimes also called dosage. Dose rates are often expressed on a per-unit-body-weight basis, yielding units such as mg/kg/day (mg/kg-day). They are also often expressed as averages over some time period, for example a lifetime.

Dose-response assessment - The determination of the relationship between the magnitude of administered, applied, or internal dose and a specific biological response. Response can be

expressed as measured or observed incidence, percent response in groups of subjects (or populations), or the probability of occurrence of a response in a population.

Dose-response curve - A graphical representation of the quantitative relationship between administered, applied, or internal dose of a chemical or agent, and a specific biological response to that chemical or agent.

Dose-response relationship - The resulting biological responses in an organ or organism expressed as a function of a series of different doses.

Dosimeter - Instrument to measure dose; many so-called dosimeters actually measure exposure rather than dose.

Dosimetry - Process of measuring or estimating dose.

Ecological exposure - Exposure of a nonhuman receptor or organism to a chemical, or a radiological or biological agent.

Effluent - Waste material being discharged into the environment, either treated or untreated. Effluent generally is used to describe water discharges to the environment, although it can refer to stack emissions or other material flowing into the environment.

Environmental fate - The destiny of a chemical or biological pollutant after release into the environment. Environmental fate involves temporal and spatial considerations of transport, transfer, storage, and transformation.

Environmental fate model - In the context of exposure assessment, any mathematical abstraction of a physical system used to predict the concentration of specific chemicals as a function of space and time subject to transport, intermedia transfer, storage, and degradation in the environment.

Environmental medium - One of the major categories of material found in the physical environment that surrounds or contacts organisms (e.g., surface water, ground water, soil, or air) and through which chemicals or pollutants can move and reach the organisms. (See ambient medium, biological medium)

Exposure - Contact of a chemical, physical, or biological agent with the outer boundary of an organism. Exposure is quantified as the concentration of the agent in the medium in contact integrated over the time duration of that contact.

Exposure assessment - The determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure.

Exposure concentration - The concentration of a chemical in its transport or carrier medium at the point of contact.

Exposure pathway - The physical course a chemical or pollutant takes from the source to the organism exposed.

Exposure route - The way a chemical or pollutant enters an organism after contact (e.g., by ingestion, inhalation, or dermal absorption).

Exposure scenario - A set of facts, assumptions, and inferences about how exposure takes place that aids the exposure assessor in evaluating, estimating, or quantifying exposures.

Fixed-location monitoring - Sampling of an environmental or ambient medium for pollutant concentration at one location continuously or repeatedly over some length of time.

Geometric mean - The n root of the product of n values.

Guidelines - Principles and procedures to set basic requirements for general limits of acceptability for assessments.

Hazard identification - A description of the potential health effects attributable to a specific chemical or physical agent. For carcinogen assessments, the hazard identification phase of a risk assessment is also used to determine whether a particular agent or chemical is, or is not, causally linked to cancer in humans.

High-end exposure (dose) estimate - A plausible estimate of individual exposure or dose for those persons at the upper end of an exposure or dose distribution, conceptually above the 90 percentile, but not higher than the individual in the population who has the highest exposure or dose.

High-end Risk Descriptor - A plausible estimate of the individual risk for those persons at the upper end of the risk distribution, conceptually above the 90 percentile but not higher than the individual in the population with the highest risk. Note that persons in the high end of the risk distribution have high risk due to high exposure, high susceptibility, or other reasons, and therefore persons in the high end of the exposure or dose distribution are not necessarily the same individuals as those in the high end of the risk distribution.

Hydrolysis - The measure of a chemical's ability to undergo a cleavage reaction with water. This property is also an indirect measurement of a chemical's stability in water. This chemical property can be expressed as a half-life value ($t_{1/2}$) in units of time or as a reaction rate constant (k) in units of $time^{-1}$.

Intake - The process by which a substance crosses the outer boundary of an organism without passing an absorption barrier (e.g., through ingestion or inhalation). (See also potential dose)

Internal dose - The amount of a substance penetrating across the absorption barriers (the exchange boundaries) of an organism, via either physical or biological processes. For the purpose of these Guidelines, this term is synonymous with absorbed dose.

Limit of detection (LOD) [or Method detection limit (MDL)] - The minimum concentration of an analyte that, in a given matrix and with a specific method, has a 99% probability of being identified, qualitatively or quantitatively measured, and reported to be greater than zero.

Matrix - A specific type of medium (e.g., surface water, drinking water) in which the analyte of interest may be contained.

Maximally exposed individual (MEI) - The single individual with the highest exposure in a given population (also, maximum exposed individual). This term has historically been defined various ways, including as defined here and also synonymously with worst case or bounding estimate. Assessors are cautioned to look for contextual definitions when encountering this term in the literature.

Maximum exposure range - A semiquantitative term referring to the extreme uppermost portion of the distribution of exposures. For consistency, this term (and the dose or risk analogues) should refer to the portion of the individual exposure distribution that conceptually falls above about the 98 percentile of the distribution, but is not higher than the individual with the highest exposure.

Median value - The value in a measurement data set such that half the measured values are greater and half are less.

Microenvironment method - A method used in predictive exposure assessments to estimate exposures by sequentially assessing exposure for a series of areas (microenvironments) that can be approximated by constant or well-characterized concentrations of a chemical or other agent.

Microenvironments - Well-defined surroundings such as the home, office, automobile, kitchen, store, etc., that can be treated as homogeneous (or well characterized) in the concentrations of a chemical or other agent.

Mode - The value in the data set that occurs most frequently.

Model Algorithm - Mathematical expression(s) and assumption(s) that are used to quantitatively predict chemical state, exposure, or other parameters.

Monte Carlo technique - A repeated random sampling from the distribution of values for each of the parameters in a generic (exposure or dose) equation to derive an estimate of the distribution of (exposures or doses in) the population.

Nonparametric statistical methods - Methods that do not assume a functional form with identifiable parameters for the statistical distribution of interest (distribution-free methods).

Pathway - The physical course a chemical or pollutant takes from the source to the organism exposed.

Personal measurement - A measurement collected from an individual's immediate environment using active or passive devices to collect the samples.

Pharmacokinetics - The study of the time course of absorption, distribution, metabolism, and excretion of a foreign substance (e.g., a drug or pollutant) in an organism's body.

Photolysis - The measure of a chemical's ability to undergo reactions brought about by light. This chemical property can be expressed as a half-life value ($t_{1/2}$) in units of time or as a reaction rate constant (k) in units of $time^{-1}$.

Point-of-contact measurement of exposure - An approach to quantifying exposure by taking measurements of concentration over time at or near the point of contact between the chemical and an organism while the exposure is taking place.

Potential dose - The amount of a chemical contained in material ingested, air breathed, or bulk material applied to the skin.

Precision - A measure of the reproducibility of a measured value under a given set of conditions.

Probability samples - Samples selected from a statistical population such that each sample has a known probability of being selected.

Quality assurance (QA) - An integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

Quality control (QC) - The overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of the users. The aim is to provide quality that is satisfactory, adequate, dependable, and economical.

Quantification limit (QL) - The concentration of analyte in a specific matrix for which the probability of producing analytical values above the method detection limit is 99%.

Random samples - Samples selected from a statistical population such that each sample has an equal probability of being selected.

Range - The difference between the largest and smallest values in a measurement data set.

Reasonable worst case - A semiquantitative term referring to the lower portion of the high end of the exposure, dose, or risk distribution. The reasonable worst case has historically been loosely defined, including synonymously with maximum exposure or worst case, and assessors are cautioned to look for contextual definitions when encountering this term in the literature. As a semiquantitative term, it is sometimes useful to refer to individual exposures, doses, or risks that, while in the high end of the distribution, are not in the extreme tail. For consistency, it

should refer to a range that can conceptually be described as above the 90 percentile in the distribution, but below about the 98 percentile. (compare maximum exposure range, worst case).

Reconstruction of dose - An approach to quantifying exposure from internal dose, which is in turn reconstructed after exposure has occurred, from evidence within an organism such as chemical levels in tissues or fluids or from evidence of other biomarkers of exposure.

Representativeness - The degree to which a sample is, or samples are, characteristic of the whole medium, exposure, or dose for which the samples are being used to make inferences.

Risk - The probability of deleterious health or environmental effects.

Risk characterization - The description of the nature and often the magnitude of human or nonhuman risk, including attendant uncertainty.

Route - The way a chemical or pollutant enters an organism after contact (e.g., by ingestion, inhalation, or dermal absorption).

Sample - A small part of something designed to show the nature or quality of the whole. Exposure-related measurements are usually samples of environmental or ambient media, exposures of a small subset of a population for a short time, or biological samples, all for the purpose of inferring the nature and quality of parameters important to evaluating exposure.

Sampling frequency - The time interval between the collection of successive samples.

Sampling plan - A set of rules or procedures specifying how a sample is to be selected and handled.

Scenario evaluation - An approach to quantifying exposure by measurement or estimation of both the amount of a substance contacted, and the frequency/duration of contact, and subsequently linking these together to estimate exposure or dose.

Source characterization measurements - Measurements made to characterize the rate of release of agents into the environment from a source of emission such as an incinerator, landfill, industrial or municipal facility, consumer product, etc.

Standard operating procedure (SOP) - A procedure adopted for repetitive use when performing a specific measurement or sampling operation.

Statistical control - The process by which the variability of measurements or of data outputs of a system is controlled to the extent necessary to produce stable and reproducible results. To say that measurements are under statistical control means that there is statistical evidence that the critical variables in the measurement process are being controlled to such an extent that the system yields data that are reproducible within well-defined limits.

Statistical significance - An inference that the probability is low that the observed difference in quantities being measured could be due to variability in the data rather than an actual difference in the quantities themselves. The inference that an observed difference is statistically significant is typically based on a test to reject one hypothesis and accept another.

Surrogate data - Substitute data or measurements on one substance used to estimate analogous or corresponding values of another substance.

Transport/Distribution - The measure of a chemical's affinity to partition to the different media it contacts (i.e., water, air, soil, and sediment) at steady state. The distribution of the chemical among the various media is normally expressed as a percentage of the mass of the chemical in the different media.

Uptake - The process by which a substance crosses an absorption barrier and is absorbed into the body.

Worst case - A semiquantitative term referring to the maximum possible exposure, dose, or risk, that can conceivably occur, whether or not this exposure, dose, or risk actually occurs or is observed in a specific population. Historically, this term has been loosely defined in an *ad hoc* way in the literature, so assessors are cautioned to look for contextual definitions when encountering this term. It should refer to a hypothetical situation in which everything that can plausibly happen to maximize exposure, dose, or risk does in fact happen. This worst case may occur (or even be observed) in a given population, but since it is usually a very unlikely set of circumstances, in most cases, a worst-case estimate will be somewhat higher than occurs in a specific population. As in other fields, the worst-case scenario is a useful device when low probability events may result in a catastrophe that must be avoided even at great cost, but in most health risk assessments, a worst-case scenario is essentially a type of bounding estimate.